Quality Assurance Certificate

	Minisart® NML
Order no.	16534----------K
Filter material	SFCA
Use before	12 / 2027
Pore size	0.20 µm
Lot no.	241559103

Minisart Syringe Filters are manufactured under a Quality Management System certified by an accredited Notified Body according to the EN ISO 13485 Standard for Medical Devices and to ISO 9001 Quality System Standard.

CE
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Each unit is tested 100% during manufacture by camera check and housing integrity by a leakage test under automatic conditions. Before packing, samples of each lot were checked by visual inspection.

Minisart is biocompatible according to ISO 10993 series.

In addition, Minisart is CE marked according to Medical Device Directive 93/42/EEC Annex II, class IIa.

Each lot has been sampled, tested and released by Quality Department for the following specifications:

Burst Pressure Test (In-Process Control)

Bubble Point Test

Endotoxine Test

Pressure Hold Test (In-Process Control)

Flow Rate Performance

Sterile Filtration Capability (Bacterial Challenge Test)

This product was sterilized using a validated process following EN ISO 11135 regulations.

Dr. Anna Vreemann
Site Quality Manager

Manufactured by Sartorius Stedim Biotech GmbH
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